IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

Kenneth H. Grabstein, Dean K. Pettit and

Raymond J. Paxton

Docket No.:

2831-E

Group Art Unit:

1645

3erial No: 09/578,669

Examiner:

Navarro, A. M.

Filed:

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For:

ANTAGONISTS OF INTERLEUKIN-15

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REMARKS

Sir:

receptor."

In response to the final Office Action dated May 20, 2003 (Paper No.13). reconsideration of the present application in view of the following remarks is respectfully requested.

REJECTION UNDER 35 U.S.C. §103

The examiner maintains the rejection of claims 26-29, 35-38, 40-44 and 46 under 35 U.S.C. § 103 as allegedly being unpatentable over Giri et al. and Grabstein et al. in view of Ferrara et al. and Hakimi et al.

The examiner maintains the rejection alleging that applicants' arguments are not fully persuasive, for the following reasons. First, the examiner asserts that he relied upon the teaching of the cited references for both the suggestion and reasonable expectation. Second, the examiner asserts that one cannot show non-obviousness by attacking references individually where the rejection was based on the combined references. Third, the examiner alleges that the antagonist as claimed is "readily apparent" as taught by the combination of the cited references. And finally, the examiner asserts that the "motivation" statement is found in Hakimi et al., in particular citing that it "teaches that proteins conjugated with PEG result in a substantial loss of protein binding to its

Reply to Final Office Action of May 20, 2003

Applicants respectfully traverse the grounds of this rejection and submit that the cited references, alone or in combination, neither teaches nor suggests the instant claims. Again, applicants submit that none of the cited references teaches or suggests the IL-15 antagonist as presently claimed; nor do any combinations of the cited references. The examiner can only offer the following grounds to support his conclusion of obviousness, as stated in the following two statements: (1) "Clearly, one of ordinary skill in the art would be motivated to inhibit the activity of IL-15 in patients with GVHD, given that inhibiting IL-2 has been shown to work, and that IL-15 and IL-2 have shared bioactivities." (2) "Hakimi et al. teaches that proteins conjugated with PEG result in a substantial loss of protein binding to its receptor." Applicants respectfully submit that these two statements are not sufficient to provide a reasonable motivation for the examiner to make a proper prima facie obviousness rejection. That is while the first statement provides at best an obvious-to-experiment standard, which is prohibited by the court, the second statement teaches away from the instant claims. In that vein, applicants request the examiner to note the distinction between the claims and the cited references, in particular Hakimi et al. While the conjugate taught by Hakimi et al. results in a substantial loss of protein binding to its receptor, the instantly claimed antagonist is capable of binding to IL-15 receptor complex.

Assuming *arguendo* that the cited references may have suggested an ordinary skill in the art to make the instant claims, Applicants submit that, because Hakimi et al. already teaches that proteins conjugated with PEG result in substantial loss of protein binding to its receptor, they provide no reasonable expectation that the invention as claimed will be a success. There is no record in the file history that the examiner has <u>established</u> a reasonable of expectation of success to support the obviousness rejection.

Applicants therefore respectfully request that in view of the above remarks, this rejection should be withdrawn and a timely Notice of Allowance should be issued for this case.

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Respectfully submitted,

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